REMARKS

No claims have been amended.

Claims 24, 28 and 30-49 remain pending, of which claims 28 and 36 were withdrawn from consideration by the Examiner.

RESPONSE TO PENDING REJECTIONS

1. Election/Restriction

On page 3 of the Office Action, the Examiner has withdrawn claims 28 and 36 from examination at this time as they are purportedly "drawn to antibodies raised against immunoglobulin light chain and to monoclonal antibodies reactive with immunoglobulin light chain..." Applicants respectfully submit that the withdrawn status of these claims as directed to non-elected species is mistaken and request that claims 28 and 36 be properly examined at this time.

Going back to the original species election, Applicants elected the species of "immunoglobulin reactive with a non-light chain amyloid as the functional species" on February 22, 2002. Applicants respectfully submit that the subject matter of claims 28 and 36 is directed to this reactive species, regardless of the source of fibrils from which the antibodies were raised. As discussed in the instant application, antibodies raised against immunoglobulin light chain (claim 28), such as the deposited antibodies of claim 36, react with non-light chain amyloid and are elected species. For instance, the specification at page 20, lines 7-14, teaches that antibodies raised against immunoglobulin light chain fibrils react against AA-amyloid as well as fibrils made from Aβ protein (both non-light chain amyloid as originally elected). Without being limited to any specific mechanism of action, the specification discloses that, for instance, the three deposited monoclonals (those same deposits as set forth in claim 36) recognize an epitope(s) that "may be a general feature of amyloids." (page 18, lines 17-21, see also Example 6). Applicants respectfully request that claims 28 and 36 be rejoined with the elected claims currently under examination.

2. The rejection of claims 24, 30-35 and 37-49 under 35 U.S.C. § 102(e) as being anticipated by Schenk et al. (U.S. Patents 6,743,427 and 6,787,523).

Applicants attach as Appendix A to this Response, a declaration under 37 C.F.R. § 1.131 from the named inventors establishing that the subject matter of the pending claims was invented in the U.S. prior to the earliest asserted priority date of the '427 and '523 patents (December 2, 1997). As set forth in declaration, the named inventors both conceived and reduced to practice the subject matter of the pending claims prior to December 2, 1997. Accordingly, Applicants respectfully request that the pending rejection be withdrawn.

3. The rejection of claims 24, 30-31, 35, 39-46 and 48-49 as being anticipated under 35 U.S.C. § 102(b) by Konig et al. (WO 96/25435).

Applicants have reviewed the Examiner's restatement of the pending rejection and reasoning concerning the maintenance of this rejection. Applicant's appreciate the time and effort on the part of the Examiner to clarify her perceived issues concerning the disclosure of the Konig *et al.* published application as well as the question as to whether Konig *et al.* provide an enabling disclosure so as to qualify as prior art under § 102.

Applicants submit that the sufficiency of the Office's *prima facie* case of anticipation hinges on the following two issues: (1) whether Konig *et al.* teach each and every limitation of the claimed invention; and (2) whether Konig *et al.* provide an enabling disclosure that allows one of ordinary skill in the art to practice the invention. Applicant's respectfully submit that the Konig *et al.* publication fails on the first count and that the question of enablement need not be further discussed at this time.

As to the teachings of Konig *et al.*, Applicants respectfully submit that the published application fails to provide any discussion of the amount of antibody that is to be administered to a patient to achieve the recited endpoint, namely the removal of amyloid deposits. A careful review of Konig *et al.* reveals that the publication merely provides unsupported assertions that the disclosed monoclonal antibody "provides for methods for the prevention of aggregation of

BA4 peptide by administering monoclonal antibody of the invention: (page 7, lines 21-23, emphasis added). Applicants respectfully submit that the prevention of aggregation of amyloid is a different process than the claimed removal. In only two other paragraphs of Konig *et al.* is any mention made of a potential therapy (the term "therapeutic" is found on page 14, line 11 and on page 25, line 15). This is the sum total of disclosure of any therapy in the Konig *et al.* publication. As such, Konig *et al.* fail to teach the limitation of an amount of antibody "effective to remove amyloid deposits" as present in each of the pending claims. On this issue alone, Konig *et al.* fail to anticipate the claimed invention and the rejection should be withdrawn.

Concerning the disclosure of Konig *et al.* in relation to the requirement that an anticipatory reference needs to meet the standards of 35 U.S.C. § 112, the Federal Circuit has recently issued a number of potentially relevant opinions. In 2001, the Federal Circuit held that a reference anticipated a claimed method of treatment by disclosing all of the steps as claimed even though the reference did not disclose the claimed clinical outcome. *See Bristol-Myers Squibb Co. v. Ben Venue Laboratories* 246 F.3d 1368, 1377 (Fed. Cir. 2001). More recently, the Federal Circuit reiterated that a reference need not demonstrate utility in order to serve as an anticipatory reference. *See. Rasmusson v. SmithKline Beecham Corp.* [Insert Cite] (Fed. Cir. 2005). In both decisions, however, the references held to be anticipatory disclosed literally or inherently each and every limitation of the claims, including the claimed dosages. *Bristol-Myers* at 1378. In the present case, as discussed above, Konig *et al.* fail to teach a key limitation of the pending claims, "an amount effective to remove amyloid deposits" and therefore, the published *Konig* application does not anticipate the claimed invention. Accordingly, Applicants at this time have not further addressed the question of whether Konig *et al.* provide an enabling disclosure sufficient to anticipate the claims.

4. The rejection of claims 24, 30-35 and 37-49 as being anticipated under 35 U.S.C. § 102(b) by Nettleship et al. (EP 613,007).

Applicants respectfully submit that the Nettleship *et al.* published application also fails to provide any discussion of the amount of antibody that is to be administered to a patient to

achieve the recited endpoint, namely the removal of amyloid deposits. At best, Nettleship *et al.* disclose that "antibodies of the invention are useful...treatment of mammals suffering from Alzheimer's disease" (column 8, lines 16-19). As such and similar to the discussion above relevant to Konig *et al.*, Nettleship *et al.* also fail to teach a key limitation of the pending claims, "an amount effective to remove amyloid deposits" and the published application does not anticipate the claimed invention. Withdrawal of the rejection is in order.[1]

5. The rejection of claims 24, 30-35 and 37-49 as being obvious under 35 U.S.C. § 103(a) over Konig et al., Nettleship et al., Schenk et al. and the Benjamani text.

As discussed above, the Schenk patents are not prior art against the pending claims. Further, the Benjamani text fails to disclose what Konig *et al.* and Nettleship *et al.* lack, *.i.e.*, the administration of an effective amount of antibody that removes amyloid deposits. As such, none of the cited reference teach this critical limitation and the combined teachings of the cited references cannot render the pending claims obvious. Applicants respectfully request that the pending rejection be withdrawn.

CONCLUSIONS

Applicants respectfully submit that the pending claims are now in condition for allowance The Examiner is hereby invited to contact the undersigned for any remaining issues.

[1] Applicants at this time have not further addressed the question of whether Nettleship *et al.* provide an enabling disclosure sufficient to anticipate the claims as Nettleship fails to teach all of the limitations of the pending claims.

Respectfully submitted,
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